

Remarks:

The amendments above and these remarks are responsive to the non-final Office action dated May 4, 2007, and are being filed under 37 C.F.R. § 1.111. Prior to this response, claims 1-7, 9-23, and 46-52 were pending in the application. In the Office action, the Examiner rejected each of the pending claims as being anticipated by or obvious over U.S. Patent No. 6,810,873 to Haikarainen et al. ("Haikarainen") alone or in combination with another reference.

Applicants traverse the rejections, contending that each of the pending claims is patentable over the cited references; taken alone or in combination. Nevertheless, to expedite the issuance of a patent, and to more particularly point out and distinctly claim aspects of the invention that applicants would like to patent now, applicants have (1) canceled claims 2, 16-23, and 49-52 without prejudice; (2) amended claims 1, 3-5, 9-13, 46, and 47; and (3) added new claims 53-57. However, applicants reserve the right to pursue the subject matter of any of the canceled claims and/or amended claims in original and/or previously presented form at a later time. Furthermore, applicants have presented remarks showing that claims 1, 3-7, 9-15, 46-48, and 53-57 are patentable over the cited references. Accordingly, in view of the foregoing amendments and the following remarks, applicants respectfully request reconsideration of the application and allowance of all of the pending claims.

I. Information Disclosure Statement

The Examiner stated that the Information Disclosure Statement filed on January 12, 2004, fails to comply with 37 C.F.R. § 1.98(a)(2), apparently for failing to supply a legible copy of one or more of the disclosed documents. In response, applicants have submitted a replacement Information Disclosure Statement with the present communication. The replacement Information Disclosure Statement includes a legible copy of each disclosed document for which a legible copy is required according to 37 C.F.R. § 1.98(a)(2). Applicants respectfully request that the Examiner consider the contents of each of the documents disclosed in the replacement Information Disclosure Statement.

II. Amendments to the Claims

The present communication amends claims 1, 3-5, 9-13, 46, and 47, and adds new claims 53-57. Each of the amendments to the claims is fully supported by the application. Exemplary support (or an explanation) for each amendment is provided, without limitation, in the following table:

<i>Claim(s)</i>	<i>Exemplary Support (or Explanation)</i>
1 (Independent)	Claim 2
3-5, 9-13, 46, and 47	(Address formal matters created by the amendments to claim 1)
53 (New)	Page 14, lines 25-29
54 (New)	Page 10, lines 24-29; Page 17, line 25, to page 18, line 7; Claim 19
55-57 (New)	Page 17, line 20, to page 18, line 12

III. Claim Rejection - 35 U.S.C. §§ 102 and 103

The Examiner rejected claim 1 under 35 U.S.C. § 102(b) as being anticipated by Haikarainen. Applicants traverse the rejection, contending that claim 1 is patentable over the cited reference. Nevertheless, for the reasons set forth above, applicants have amended independent claim 1 to correspond to claim 2, and have canceled claim 2 without prejudice. The rejection of claim 1 as being anticipated is thus moot.

Independent claim 1 is directed to a method and, as amended, reads as follow:

1. (Currently Amended) A method of dispensing one or more medicaments, comprising:

providing a treatment plan having at least two rates of action for one or more medicaments;

selecting a different droplet size characteristic corresponding to each of the at least two rates of action; and

ejecting medicament droplets having each different droplet size characteristic into a respiratory system of a subject according to the treatment plan, thereby allowing the one or more medicaments to act at two or more rates.

Independent claim 1, as amended, corresponds to claim 2, which was rejected in the Office action as being unpatentable over a combination of Haikarainen and U.S. Patent No. 5,915,377 to Coffee ("Coffee"). Applicants traverse the rejection because the Examiner has not met the burden of establishing a *prime facie* case of obviousness: (1) neither reference, alone or in combination, discloses every element of the claim, such as selecting different droplet sizes in correspondence with at least two rates of action of a treatment plan, and (2) it would not have been obvious to combine the references.

Haikarainen relates to an inhaler for the dispensing of a powdered medicament for inhalation. Figure 1 of Haikarainen, which is reproduced here to facilitate review, illustrates an example of the inhaler. The inhaler includes a pair of medicament containers 1, 2 filled with powdered medicament. In use, a dose of each powdered medicament is received in dosing recesses 7a, 7b of a rotatable metering drum 6 from the respective medicament containers and then is aerosolized into an aerosolization channel for inhalation.

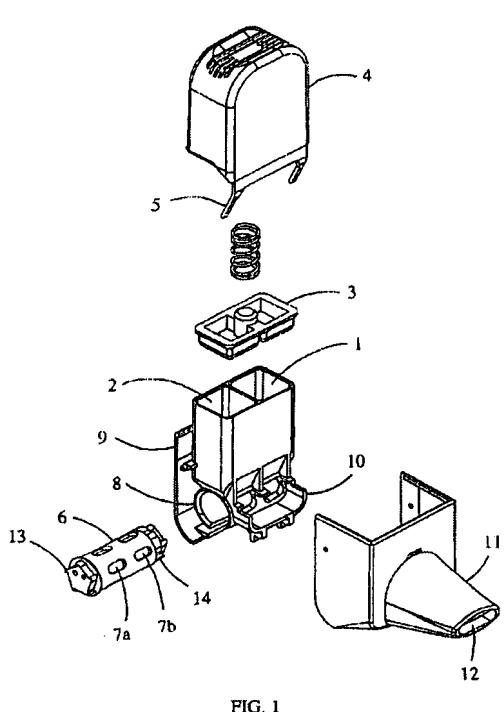


FIG. 1

Since the medicament is powdered, Haikarainen involves the dispensing of solid particles, not droplets (which are fluid-based). In addition, Haikarainen does not provide any disclosure regarding the size of the medicament particles, and particularly not regarding any difference in size for the particles of medicament powders in the pair of

medicament containers. Furthermore, Haikarainen does not disclose, teach, or suggest any mechanism for adjusting the size of the particles provided by the medicament powders.

Nevertheless, in the Office action, the Examiner asserted that "it would be evident that each droplet is going to have a droplet size comparable to that of the dosing recess" (page 4, lines 10 and 11). Applicants strongly disagree. Haikarainen does not involve dispensing droplets at all. Even if the aerosolized powders of Haikarainen are construed as being droplets, which applicants contend is repugnant to the intended meaning of the term "droplet," each recess 7a, 7b of Haikarainen determines the amount of medicament powder that is transferred from container 1 or 2 to the aerosolization channel as drum 6 is rotated, not the size of individual particles. Therefore, Haikarainen does not disclose, teach, or suggest selecting or ejecting different droplet sizes, as recited by amended claim 1. Haikarainen thus particularly does not disclose selecting different droplet sizes in correspondence with at least two rates of action of a treatment plan, as recited by amended claim 1.

Coffee relates to a dispensing device for producing multiple comminutions of opposing polarities. Figure 7 of Coffee, which is reproduced here to facilitate review, illustrates a disclosed dispensing device. The device includes a pair of capillary-tube nozzles 24 that generate droplets of opposing polarity from a pair of reservoirs 20. Due to the opposing polarity, "[t]he droplets will then be attracted to each other by electric field forces, and will tend to mix vigorously to give a charged droplet spray for dispensation to the upper respiratory tract" (col. 6, lines 22-25; emphasis added). Coffee

does not disclose that the droplets of opposite polarity have different sizes, and particularly not sizes different enough to have different sites of deposition for different rates of action.

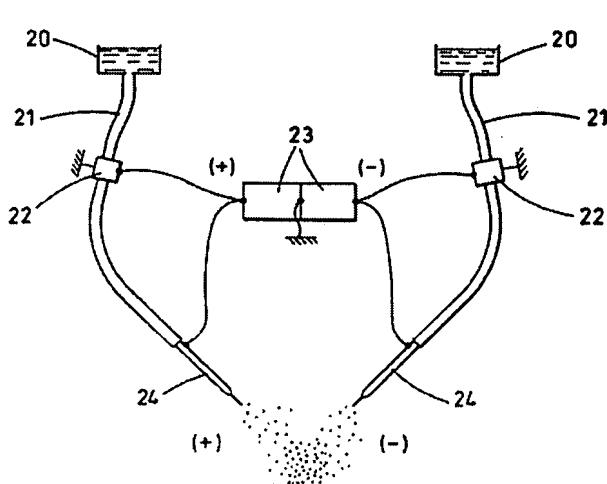


Fig. 7

Even if, for the sake of argument, Coffee is construed as disclosing different droplet sizes, and applicants contend that Coffee does not, the different droplet sizes would have no correspondence to rates of action of a treatment plan, as recited by claim 1. In particular, Coffee teaches vigorous mixing of droplets of opposite polarity to merge droplets. Accordingly, droplets of different size and opposite polarity, if generated according to the teachings of Coffee, would have been expected to merge to create larger droplets with only one site of deposition and rate of action.

It also would not have been obvious to combine Haikarainen with Coffee because these references relate to incompatible, non-combinable mechanisms for dispensing medicaments. In particular, Haikarainen relates to dispensing solid particles, whereas Coffee involves dispensing fluid droplets. Accordingly, the dispensing mechanisms disclosed by these references are alternative approaches to providing medicament administration. One of skill in the art thus would not have considered combination of these references to be practical.

In summary, independent claim 1 is patentable over Haikarainen and Coffee because these references do not disclose, teach, or suggest every element of claim 1, and because it would not have been obvious to combine these references. Claim 1 thus should be allowed. In addition, claims 3-7, 9-15, 46-48, and 53-57, which depend from claim 1, also should be allowed for at least the same reasons as claim 1.

IV. New Claims 53-57

The present communication adds new dependent claims 53-57. Each of the new claims should be allowed for depending ultimately from allowable claim 1. In addition, each of the new claims also should be allowed for further distinguishing the claimed invention from the art of record.



V. Conclusion

Applicants submit that this application is now in condition for allowance, in view of the above amendments and remarks. Accordingly, applicants respectfully request that the Examiner issue a Notice of Allowability covering all of the pending claims. If the Examiner has any questions, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on August 6, 2007.

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